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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,954	08/14/2006	Abudogupur Abudokirim	114116.00032	8400

21324 7590 01/26/2012

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EXAMINER	
BHAT, NARAYAN KAMESHWAR	
ART UNIT	PAPER NUMBER
1634	

NOTIFICATION DATE	DELIVERY MODE
01/26/2012	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/597,954	ABUDOKIRIM ET AL.	
	Examiner	Art Unit	
	NARAYAN BHAT	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1,2,5,6,10,13 and 16* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1,2,5,6,10,13 and 16* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *14 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FINAL ACTION

1. This office action is written in response to the papers filed on December 12, 2011. The amendments to claim 1 requiring new combination of method steps necessitated the new grounds of rejection presented in this office action. Accordingly, ***this action is made final.***

Claim status

2. Claims 1, 2, 5, 6, 10, 13 and 16 are pending in this application and are under prosecution. Claim 1 is amended. Claims 3, 4, 7-9, 11, 12, 14, 15 and 17-20 are cancelled. The claim amendments have been reviewed and entered.

Withdrawn Rejections and Response to the Remarks

3. The previous rejection of claims 1-16 under 35 USC 103(a) as being unpatentable over Tennikova, Hatch and Sauer has been withdrawn in view of the claim amendments and cancellation of claims 3, 4, 7-9, 11, 12, 14, 15. The arguments filed on December 12, 2011 regarding the said rejection have been fully considered (Remarks, pgs. 4-6) and are moot in view of the withdrawn rejection necessitated by the claim amendments and cancellation of claims 3, 4, 7-9, 11, 12, 14, 15. The arguments regarding the teachings of Tennikova and Hatch as it pertains to the rejection made in this office action are addressed below.

The arguments regarding the said 103(a) rejection are directed to Hatch not teaching the use of different pore sizes in a monolith structure but rather teaches different spacing between particles in a traditional, packed bed chromatography column (Remarks, pg. 5, first paragraph).

The Examiner acknowledges that teachings Hatch of interstitial distance for separation of DNA was an oversight on part of the Examiner. The Examiner also acknowledges that Hatch does not specifically teach selecting different pore sizes corresponding to the size of the nucleic acid in a monolith structure. However, as discussed below in section 7, Kitamura teaches selecting different pore sizes corresponding to the size of the nucleic acid and provides motivation to modify the monolith structure Tennikova in view of Hatch for including pore sizes corresponding to the size of the nucleic acid for separating large quantities of nucleic acids in a shorter time. Therefore the limitation of selecting the diameters of the macropores according to the size of the nucleic acid to be purified is obvious over Tennikova in view of hatch and further in view of Kitamura.

Applicant further argues that Hatch teaches away from the applying lessons of column chromatography to monolith structures (Remarks, pg. 5 and paragraph 2).

These arguments are not persuasive because Hatch discusses the lesson learnt from the nonporous particles (column 3, lines 17-61) and one having ordinary skill in the art would recognize that lessons learnt from the nonporous particles can't be applied to porous monolithic structures.

Applicant further reiterates the arguments that Hatch does not teach or suggest selecting the diameter of macropores in the monolith according to the size of the nucleic acid to be purified have been fully considered (Remarks, pg. 5 and paragraph 3).

These arguments are not persuasive for the same reasons as discussed above.

Applicant further argues that Hatch does not teach or suggest the presence of micropores within the macropores as recited in amended claim 1. Hatch only discloses one set of macropores, "...the present invention will have pores in the less than 5,000 nm range, down to about 10 nm (column 8, line 2-3)." This does not teach or suggest

micro-pores within macro-pores as recited in the instant claims. Additionally, neither Tennikova nor Sauer is observed to provide such a teaching or suggestion (Remarks, pg. 5, last paragraph and pg. 6, first paragraph).

These arguments are not persuasive because instant pending claims are rejected over Tennikova in view of Hatch and further in view of Kitamura. Therefore arguments attacking references individually are not persuasive especially when rejection is made using combination of references. Furthermore, courts have ruled that the arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references are not persuasive (See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986)). In the instant case, Tennikova teaches that the average macropore size (i.e., diameter) is about 0.5 um (Fig. 3b and pg. 32, column 2, paragraph 1, line 6). Tennikova also teaches that the porous body of the monolith structure has micropores (i.e., small globules or mesopores) in the macropores (Fig, 3b and pg. 29, column 1, paragraph 1). One having ordinary skill in the art would recognize that the diameter of the micropore within the macropore of average diameter of 500 nm of Tennikova is at least less than 500 nm.

Furthermore, as acknowledged by the Applicant Hatch teaches monolith structures comprising larger pores of 5 um and pores having 10 nm in the monolithic structure. Hatch also teaches that the microscopic exam revealed that a typical matrix of the invention includes small globules of about 1-2 microns in diameter that are fused into continuous structures with pores in the 1-5 micron size range (column 8, lines 13-

19), thus teaching micropores (i.e., small globules) in the macropore. The combined teachings of small globules (i.e., micropores) within the macropore Tennikova in view of Hatch encompasses the claimed size of the micropore

Also, it is noted that the courts have stated where the claimed ranges "overlap or lie inside the ranged disclosed by the prior art" and even when the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have similar properties, a prima facie case of obviousness exists (see In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990); Titanium Metals Corp. of America v. Banner, 778 F2d 775. 227 USPQ 773 (Fed. Cir. 1985) (see MPEP 2144.05.01). In the instant case monolith comprising micropores within macropores were known in the art at the time the claimed invention was made. Therefore, the claimed diameter of the micropore less than or equal to 100 nm with the macropore is an obvious variant of the diameter of the micropore less than 500nm as taught by the prior art of Tennikova. For these reasons arguments of Tennikova or Hatch does not teach or suggest micropores in the macropore are not persuasive.

It is maintained that all the elements of claims 1, 2, 5, 6, 10, 13 and 16 are obvious over Tennikova in view of Hatch and further in view of Kitamura. Furthermore, selecting the size of the pore according to the size of the nucleic acids is also very well established in the gel filtration chromatography art as exemplified by Kitamura.

Claim Interpretation

4. The apparatus of claim 1 recite features both structurally and functionally. However, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function (In re Schreiber, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997), MPEP 2114). Therefore instant claims are rejected over the structural components taught in the prior art rather than their intended use.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following rejection is necessitated by the claim amendments.

7. Claims 1, 2, 5, 6, 10, 13 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tennikova et al (J. High Resol. Chromatogr., 2000, 23, 27-38, cited in the previous office action) in view of Hatch (USPN 6,238,565 issued May 29, 2001, cited in the previous office action) and further in view of Kitamura (US 2001/0007026 published Jul. 5, 2001). The size of the pUC18 digested with MSP I restriction enzyme of Hatch is further evidenced by New England Biolabs custom digest data brochure (Down loaded from the internet http://tools.neb.com/NEBcutter2, printed on June 15, 2011)

Tennikova, Hatch and Kitamura teach an apparatus for separating and purifying nucleic acids and therefore are analogous arts.

The apparatus of claim 1 has following structural components: a) an integral monolith structure comprising macro-pores continuously extending from one end of the monolith structure to the other end and corresponding to the sizes of nucleic acids, b) the macropores having a diameters of about 10 nm to about 100 nm or about 100 nm to about 1 um or about 1 um to about 10 um or about 10 um to about 100 um and wherein the porous body of the monolith structure contains the micropores having a diameter of less than or equal to 100 nm in the macropores and c) the diameter range of the macropore is selected according to the size of the nucleic acid to be purified.

Regarding claim 1, Tennikova teaches an apparatus for separating and purifying nucleic acids comprising following structural components (Fig. 4, right panel).

Regarding an integral monolith structure, Tennikova teaches an integral monolith structure (i.e., monolithic continuous structure), wherein macropores continuously

extending from one end of the monolith structure to the other end (Fig. 4, right panel, and Abstract, pg. 29, column 2, paragraph 3, pg. 32, column 2, paragraph 2).

With regard to the limitation of "the monolith structure corresponding to the sizes of nucleic acids and configured so that nucleic acids corresponding to the macropores can be retained respectively by allowing a solution containing nucleic acids to be separated to pass there through" it is noted that the instant claim as recited do not require nucleic acids as the structural components of the claimed apparatus, but rather capable of separating the size of the nucleic acids. Furthermore, instant claim 1 as recited does not require a plurality of integral monolith structure each specific for a particular size nucleic acid.

With regard to above said limitations, Tennikova teaches that the monolith structure is configured so that nucleic acids corresponding to macropore of 0.5 um can be retained by allowing a solution containing nucleic acids (i.e., different size oligonucleotides) to be separated to pass there through (Fig. 7, see the legend and pg. 32, column 2, paragraph 2 and pg. 33, column 2 and paragraph 1). Tennikova does not specifically teach that the monolith structure corresponds to the sizes of the nucleic acids.

Regarding the diameter of macro pores and micropores, Tennikova teaches that the average macropore size, (i.e., diameter) is about 0.5 um (Fig. 3b and pg. 32, column 2, paragraph 1, line 6). The diameter of the macropore of about 500 nm is in the range of about 100 nm to about 1 um. Tennikova also teaches that the porous body of the monolith structure has micropores (i.e., small globules or mesopores) in the macropores

(Fig, 3b and pg. 29, column 1, paragraph 1). One having ordinary skill in the art would recognize that the diameter of the micropore within the macropore of average diameter of 500 nm of Tennikova is at least less than 500 nm. Tennikova does not specifically teach that the micropore has a diameter of less than or equal to 100 nm.

Regarding the limitation of the macropore diameter range selected according to the size of the nucleic acid to be purified, Tennikova does not specifically teach the said limitation.

As discussed above, Tennikova does not specifically teach that the monolithic structure the micropore within the macropore has a diameter of less than or equal to 100 nm and the monolithic structure corresponding to the size of the nucleic acids and selecting the diameter range of the macropore according to the size of the nucleic acids. However, the monolithic structure comprising the micropore within the macropore having a diameter of less than or equal to 100 nm and selecting monolith structures for the separation of different size nucleic acids were known in the art at the time the claimed invention was made as taught by Hatch.

Hatch teaches an apparatus for separating and purifying nucleic acids comprising a monolithic column (i.e., an integral monolithic structure) having a pore size less than 5000 nm range to down to 10 nm range (column 8, lines 1-5), which is in the range of diameter of about 10 nm to about 100 nm, or about 100 nm to about 1 micrometer or about 1 micrometer to about 10 um. Hatch also teaches that the microscopic exam revealed that a typical matrix of the invention includes small globules of about 1-2 microns in diameter that are fused into continuous structures with pores in

the 1-5 micron size range (column 8, lines 13-19), thus teaching micropores (i.e., small globules) in the macropore. Hatch further teaches that the porous body of the monolith structure has a size of less than 10 nm (column 8, lines 1-5). One having ordinary skill in the art would recognize that macropore comprising small globules of smaller size (e.g., 10 nm pore) encompasses the micropore in the macropore.

With regard to selecting monolith structure for the separation of nucleic acids, Hatch teaches a C6 monolith for separation of shorter single stranded nucleic acids (Fig. 1 and Example 1) and a C12 monolith for separation of larger size double stranded nucleic acids derived from pUC18 DNA digested with MSP I (Fig. 2A and Example 2). The larger size double stranded nucleic acids derived from pUC18 DNA digested with MSP I is further evidenced by NEB custom digest data brochure (pg. 1). The teachings of different monoliths for separating shorter and longer size nucleic acids of Hatch encompasses selecting two different monolith structures for separation of different size nucleic acids.

Hatch also teaches that the monolith structure comprising micropores within macropores provide a surprising advantage over the existing technology and better resolution of small and large sized nucleic acids (Figs. 1 and 2 and column 4, lines 24-30), thus providing motivation to one having ordinary skill in the art to modify the monolith of Tennikova with the monolith comprising 10 nm diameter micropores within macropores of Hatch.

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the monolith of Tennikova with the

monolith comprising 10 nm diameter micropores within macropores of Hatch with a reasonable expectation of success with the expected benefit of having the monolithic structure with surprising advantage over the existing technology and providing better resolution of small and large sized nucleic acids as taught by Hatch (Figs. 1 and 2 and column 4, lines 24-30). An artisan having ordinary skill in the art would have a reasonable expectation of success because it merely involves substitution of one monolithic structure for the other which is routinely practiced in the art as exemplified by Hatch.

Regarding the limitation of "monolithic structure corresponding to size of the nucleic acids and selecting the diameter range of the macropores according to the size of the nucleic acids", as discussed above Hatch teaches a C6 monolith for separation of shorter single stranded nucleic acids (Fig. 1 and Example 1) and C12 monolith for separation of larger size double stranded nucleic acids derived from pUC18 DNA digested with MSP I (Fig. 2A and Example 2). The teachings of different monoliths for separating shorter and longer size nucleic acids of Hatch encompasses selecting two different monolith structures for separation of different size nucleic acids.

Hatch also teaches that the composition for the monolith comprises a porogen and additives, which contributes to the pore formation (column 4, lines 44-51 and column 7, lines 32-67) and the said composition for the C6 monolith are different from C12 monolith (Examples 1 and 2), thus suggesting different pore size for the C6 and C12 monoliths. Hatch also teaches selecting monolithic column having pores of about 1 um for separating 2,072, 2,647, and 3,147 base pairs DNA (column 8, lines 1-30). One

having ordinary skill in the art would recognize based on the combined teachings of suggesting different pore size for separating different size nucleic acids and selecting the monolithic column with pore diameter of 1 um for separating nucleic acids of Hatch suggests the monolithic structure corresponding to the size of the nucleic acids.

Tennikova in view of Hatch does not specifically teach selecting the diameter range of the macropores according to the size of the nucleic acids. However, selecting the diameter range of the macropores according to the size of the nucleic acids was known in the art at the time the claimed invention was made as taught by Kitamura.

Kitamura teaches a column device for the separation of nucleic acids comprising particle with a pore and further teaches that the size of the pore diameter is selected appropriately depending on the molecular size of nucleic acids designed to separate (paragraph 31, lines 17-22). Kitamura also teaches selecting large pore diameter for nucleic acids with large molecular size and a small pore diameter for nucleic acids with small molecular size (paragraph 0036). Kitamura also teaches that different pore size particles allow the separation of large quantities of nucleic acids in shorter time (Abstract and paragraph 0013).

As discussed above, both Tennikova and Hatch teach that monoliths are better than traditional particles for separation of polynucleotides (e.g., Hatch, column 4, lines 15-30). Hatch also teaches that the monoliths comprising different macropore size and selecting different monoliths (C6 and C12) for separation of different size nucleic acids. Hatch also teaches the composition comprising pore forming compounds for the C6 monolith is different from C12 monolith (Examples 1 and 2), thus implicitly suggesting

different pore size for the C6 and C12 monoliths. Kitamura explicitly teaches selecting the pore size according to the size of the nucleic acids for separating large quantities of nucleic acids in shorter time, thus providing motivation to one having ordinary skill in the art to select the pore size of the particle based on the size of the nucleic acids.

One having ordinary skill in the art would also recognize that selecting the monolith macropore size based on the size of the nucleic acid would be obvious over Tennikova in view of Hatch and further in view of Kitamura because Kitamura provides motivation to one of ordinary skill in the art to modify the monoliths of Tennikova in view of Hatch with monoliths of appropriate pore size corresponding to the size of the nucleic acids for separation of large quantities of nucleic acids in shorter time.

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to include the appropriate pore size according to the size of the nucleic acid of Kitamura to modify the monolith in the apparatus of Tennikova in view of Hatch with a reasonable expectation of success with the expected benefit of having monolithic structure of appropriate pore size for separating large quantities of nucleic acids in a shorter time as taught by Kitamura (Abstract and paragraph 0013). An artisan having ordinary skill in the art would have a reasonable expectation of success because it merely involves including monolithic structure with appropriate pore size for the corresponding size of the nucleic acids (i.e., larger pore for larger nucleic acids) which is routinely practiced in the gel filtration art as exemplified by Kitamura.

Furthermore, it is noted that in KSR, the Supreme Court particularly emphasized "the need for caution in granting a patent based on the combination of elements found in the prior art," (USPQ2d at 1395), and reaffirmed principles based on its precedent that "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." In the instant case, monolith with macropores and micropores within the macropore for separating the nucleic acids and selecting the pore size according to the size of the nucleic acids are familiar structural components known in the art at the time the claimed invention was made and when combined as suggested above known to produce the claimed apparatus (i.e., producing expected results). Therefore, the claimed apparatus are obvious over Tennikova, Hatch and Kitamura. Furthermore, selecting the size of the pore according to the size of the nucleic acids is very well established in the gel filtration chromatography art as exemplified by Kitamura.

The teachings of Tennikova, Hatch and Kitamura regarding dependent claims 2, 5, 6, 10, 13 and 16 are discussed below.

Regarding claim 2, Tennikova teaches that the monolith structure employs silica (pg. 33, section 4.1) or a hybrid material containing an organic material and silica (Fig. 3b and pg. 33, section 4.1).

Regarding claims 5 and 10, Tennikova teaches that a disc formed by monolith structure and further teaches that the disc is placed in a column tube to form a monolith solid phase column (Fig. 2, pg. 28, column 1, paragraph 2, column 2 and paragraph 3)

Regarding claims 6, 13 and 16, Tennikova teaches that the disc formed by the monolith structure (Fig. 2, pg. 28, column 1, paragraph 2) and further teaches monolith solid phase column formed by detachably attaching a base formed with the monolith structure to a cylindrical body having the top and the bottom opened (Fig. 2, See the CIM monolith disks and dedicated cartridge with open end and pg. 28, column 2, paragraph 2, lines 1-3).

Conclusion

8. No claims are allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NARAYAN BHAT whose telephone number is (571)272-5540. The examiner can normally be reached on 8.30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571)-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Narayan K. Bhat/

Examiner, Art Unit 1634

/Steven C Pohnert/

Primary Examiner, Art Unit 1634